

CLAIMS

We-claim:

- 1. A suppository composition for rectal administration of a lincosamide antibacterial drug, comprising an antimicrobially effective amount of the lincosamide dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of solid particles.
- 2. The composition of claim 1, wherein the lincosamide is present in a form selected from the group consisting of a lincosamide salt and a lincosamide ester.

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- 3. The composition of claim 1, wherein the lincosamide is present in the form of a lincosamide phosphate.
- 4. The composition of claim 1 wherein the lincosamide is present in said composition in an amount from about 0.1 % by weight of the entire composition to about 60% by weight of the entire composition.
 - 5. The composition of claim 1 wherein the lincosamide is selected from the group consisting of pirlimycin and lincomycin.

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6. The composition of claim 1 wherein the lincosamide is clindamycin.

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- of the clindamycin is present in said composition in an amount from about 1.5 % by weight of the entire composition to about 7.5% by weight of the entire composition.
- 8. The composition of claim 1 wherein said Hard Fat has a ß polymorphic form which has a flow point in the range from 30 °C to 40 °C.
- 30 9. The composition of claim 1 wherein said Hard Fat has a β polymorphic form which has a flow point of 37 °C or less.





10. The composition of claim 1 wherein the Hard Fat is a mixture of glyceride -esters-of-vegetable-C₁₂=C₁₈-saturated_fatty_acids_containing_at_least_about_50% triglyceride esters.

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- In the composition of claim 1 wherein the particles of lincosamide have particle size of $10\mu m$ or less.
- 12. The composition of claim 1 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

10 Open-tube melting point:

31.0-33.0 °C (α polymorphic form)

Solidification point:

30.0-32.5 °C (α polymorphic form)

Hydroxyl value

max. 3 mg potassium hydroxide/g

Saponification value:

240-250 mg potassium hydroxide/g

Diglycerides

max. 15% by weight

Monoglycerides

max 1% by weight.

Monogrycena

- 13. A method of rectally administering a lincosamide to a subject, comprising the steps of:
 - a) providing a suppository comprising an antimicrobially effective amount of the lincosamide, dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of particles, wherein the suppository is sufficiently small to pass through the anus of the subject; and
 - b) inserting the rectal suppository into the rectum of the subject, through the anus.

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- 14. The method of claim 13, wherein the subject is a mammal.
- 15. The method of claim 14, wherein the mammal is selected from the group consisting of a dog, a cat, a sheep, a cow, a steer, a goat, and a horse.

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16. The method of claim 14, wherein the mammal is a human being.





- 17. The method of claim 13 wherein the lincosamide is selected from the group consisting of lincomycin-and-pirlimyein.
 - 18. The method of claim 13 wherein the lincosamide is a clindamycin.

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- 19. The method of claim 13, wherein the lincosamide is present in a form selected from the group consisting of a lincosamide salt and a lincosamide ester.
- 20. The method of claim 13, wherein the lincosamide is present in the form of a lincosamide phosphate.
 - 21. The method of claim 13, wherein the lincosamide is present in the suppository in an amount from about 0.1% by weight to about 60% by weight of the entire composition.

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- 22. The method of claim 13 wherein said Hard Fat has a β polymorphic form which has a flow point in the range from 30 °C to 40 °C.
- 23. The method of claim 13 wherein said Hard Fat has a β polymorphic form which has a flow point of about 37 °C or less.
 - 24. The method of claim 13 wherein the Hard Fat is a mixture of glyceride esters of vegetable C_{12} - C_{18} saturated fatty acids containing at least about 50% triglyceride esters.

or less.

The method of claim 13 wherein the lincosamide has a particle size of $10\mu m$

26. The method of claim 13 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

Open-tube melting point:

31.0-33.0 °C (α polymorphic form)

Solidification point:

30.0-32.5 °C (α polymorphic form)





Hydroxyl value

max. 3 mg potassium hydroxide/g

Saponification value:

-240-250-mg-potassium_hydroxide/g

Diglycerides

max. 15% by weight

Monoglycerides

max 1% by weight.

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27. A method of treating a mammalian subject infected with at least one grampositive, comprising the steps of:

- a) providing a suppository comprising an antimicrobially effective amount of the lincosamide, dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of particles, wherein the suppository is sufficiently small to pass through the anus of the subject;
- b) inserting the rectal suppository into the rectum of the subject, through the anus; and
- c) repeating step (b) until the subject is cured of the infection.

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- 28. The method of claim 27, wherein the mammal is a human being.
- 29. The method of claim 27 wherein the lincosamide is selected from the group consisting of lincomycin and pirlimycin.

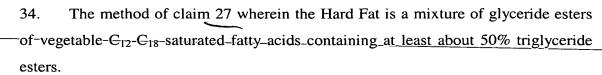
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- 30. The method of claim 27 wherein the lincosamide is a clindamycin.
- 31. The method of claim 27, wherein the lincosamide is present in a form selected from the group consisting of a lincosamide salt and a lincosamide ester.

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- 32. The method of claim 27, wherein the lincosamide is present in the form of a lincosamide phosphate.
- 33. The method of claim 27 wherein the Hard Fat has a β polymorphic form which
 30 has a flow point in the range from 30 °C to 40 °C.





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- 35. The method of claim 27 wherein the lincosamide has a particle size of $10\mu m$ or less.
- 36. The method of claim 27 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

10 Open-tube melting point: 31.0-33.0 °C (α polymorphic form)

Solidification point: 30.0-32.5 °C (α polymorphic form)

Hydroxyl value max. 3 mg potassium hydroxide/g

Saponification value: 240-250 mg potassium hydroxide/g

Diglycerides max. 15% by weight

Monoglycerides max 1% by weight.